

Maureen J. Charron and Ellen B. Katz
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Remarks

Claims 73-79, 92-94, 98-100, 104-106 and 110-112 are pending and under examination.

Rejections under 35 U.S.C. §101 and 35 U.S.C. §112, first paragraph

The claims stand rejected under 35 U.S.C. §101 and 35 U.S.C. §112, first paragraph, as allegedly lacking utility and enablement (i.e., one skilled in the art would allegedly not know how to use the claimed invention).

Applicants have previously maintained that the claimed invention has utility as a marker of breast cancer. Applicants noted that the specification discloses that GLUTx protein is expressed in mammary tumors but not in normal mammary tissue, as determined using Western blot analysis (page 38, line 30 through page 39, line 11). Applicants maintain that the specific relevant feature for this asserted utility is the change in GLUTx protein expression in cancerous breast tissue as compared to normal breast tissue, and that the presence of GLUTx expression in some other normal, non-cancerous tissues of the body, as disclosed in the application and as noted by the Examiner, is not relevant for the use of GLUTx protein as a marker for breast cancer.

Applicants have provided the amino acid sequence of the last 11 amino acids of the carboxy-terminus of the GLUTx protein that was used to generate the antibody used to detect the presence of GLUTx protein in the mammary tumor (see Specification, page 38, line 30, through page 39, line 1). The skilled artisan would know how to generate an antibody to the specified amino acid sequence and how to use the antibody to determine whether a mammary tissue sample contained GLUTx protein, where the presence of GLUTx protein in the mammary tissue is an indication that the subject has breast cancer.

In an October 22, 2003 telephone call with the undersigned attorney,

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Examiner Kaushal indicated that he would consider additional data in support of the asserted utility.

Applicants note that the claims of the subject application are directed to nucleic acids encoding GLUTx sequences in rodents (i.e. rat, mouse) and humans. As further evidence of the utility of the claimed invention, attached hereto is the publication (US2002/0038464 A1) of U.S. Patent Application No. 09/886,954, which is a continuation-in-part of the subject application. The published application US2002/0038464 A1 indicates that the invention is based on the discovery that GLUTx is overexpressed in tumors and that the invention is useful in the diagnosis, treatment, and monitoring of cancer (see paragraph [0005] on page 1). As in the subject application, published application US2002/0038464 A1 used an 11 amino acid peptide corresponding to the carboxy-terminus of GLUTx protein to generate a GLUTx-specific antibody (see paragraph [0119] on page 12). Experimental results in regard to cancer are presented in paragraphs [0146]-[0151] on pages 14-15. In paragraph [0147] it is stated that “[t]he results of the inventors’ experiments show that GLUTx is highly expressed in rodent and human cancer.” Results with mammary tumors are illustrated in Figures 1 and 2.

Thus, applicants maintain that the claimed invention fulfills the requirement of 35 U.S.C. §101 as having a “specific, substantial, and credible use ...” (MPEP 2164.07). Further, applicants maintain that the claimed invention fulfills the requirements of 35 U.S.C. §112, first paragraph, in that since the claimed invention is supported by a credible asserted utility, the skilled artisan would know how to use the claimed invention. Applicants note that an applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement (MPEP 2107 II. (B) (1) (ii)). Accordingly, applicants respectfully request that the Examiner reconsider and withdraw these rejections.

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CONCLUSIONS

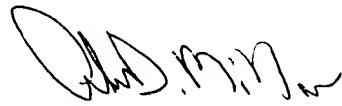
In light of the remarks made herein above, applicants respectfully request withdrawal of the rejections in the August 12, 2003 Final Office Action and passage of the pending claims to allowance. If there are any minor matters that would prevent allowance of the claims, applicants request that the Examiner contact the undersigned attorney.

No fee is deemed necessary in connection with the submission of this Communication. However, if there are any unanticipated fees required to maintain the pendency of this application, the PTO is authorized to withdraw those fees from Deposit Account 01-1785.

Respectfully submitted,

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